AACC | Better health through laboratory medicine.

October 13, 2020

Secretary Alex M. Azar II
US Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar:

The American Association for Clinical Chemistry supports your recent decision to eliminate the requirement that clinical laboratories seek emergency use authorization (EUA) from the Food and Drug Administration (FDA) prior to introducing laboratory developed tests (LDTs) to detect whether a person is infected with COVID-19. LDTs have been, and continue to be, regulated by the Centers for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments (CLIA).

We are concerned that under the CARES Act, Medicare covers only COVID-19 LDTs that are either under EUA review or have received an EUA from the FDA, or are performed in a state that has agreed to directly oversee the test (only eight states and Puerto Rico have assumed this responsibility). This means that if a lab does not currently have an EUA for its COVID-19 LDT it will not get paid by the federal government.

There appears to be language in subparagraph (D) under Section 3201 Coverage of Diagnostic Testing (see text below) of the CARES Act that would permit the Department of Health and Human Services (HHS) to pay for these COVID-19 LDTs. The law states that HHS can reimburse for "any other test that the Secretary determines appropriate in guidance." AACC urges you to utilize this authority and ensure that clinical laboratories performing LDTs to diagnose individuals with SARS-CoV-2 get reimbursed for their services. If our interpretation is incorrect, we urge you to publish a clarification on the HHS LDT FAQ page.

We look forward to working with you on this important issue. If you have any questions, please email Vince Stine, PhD, AACC's Senior Director of Government and Global Affairs, at vstine@aacc.org.

Sincerely,

David G. Grenache

David G. Grenache, PhD, D(ABCC)
President, AACC

Text from CARES Act

SEC. 3201. COVERAGE OF DIAGNOSTIC TESTING FOR COVID-19
Paragraph (1) of section 6001(a) of division F of the Families First Coronavirus Response Act (Public Law 116-127) is amended to read as follows:

``(1) An in vitro diagnostic test defined in section 809.3 of title 21, Code of Federal Regulations (or successor regulations) for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19, and the administration of such a test, that—

``(A) is approved, cleared, or authorized under section 510(k), 513, 515, or 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 360c, 360e, 360bbb-3);

``(B) the developer has requested, or intends to request, emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3), unless and until the emergency use authorization request under such section 564 has been denied or the developer of such test does not submit a request under such section within a reasonable timeframe;

`(C) is developed in and authorized by a State that has notified the Secretary of Health and Human Services of its intention to review tests intended to diagnose COVID-19; or

`(D) other test that the Secretary determines appropriate in guidance.''.